Remarks

Claim 1 was amended to delete the phrase "and having a higher potency than 1 wt% hydrocortisone." Claim 3 was amended to correct a grammatical error. New claim 17 was added. Support for claim 17 is found, for example, on page 2, lines 7-10; page 3, lines 19-21.

Rejection Under 35 U.S.C. § 112

Claim 1 was rejected under 35 U.S.C. § 112, as containing new matter. This rejection is respectfully traversed if applied to the amended claim which deletes the objected to phrase.

It is believed the rejection is in error. The specification clearly supports the use of a steroidal anti-inflammatory that is of greater potency than 1 wt% hydrocortisone, which is explicitly stated to be of little if any benefit.

However, solely to facilitate prosecution, the claims have been amended to delete the reference to low potency steroids, including 1 wt% hydrocortisone.

Rejection Under 35 U.S.C. § 102 and § 103

Claims 1-10 and 13-17 were rejected under 35 U.S.C. § 102(a) as disclosed by U. S. Patent No. 6,444,647 to Robinson *et al.* ("Robinson"). Claims 1-5, 7-13 and 17 were rejected under 35 U.S.C. § 102(b) as disclosed by U. S. Patent No. 6,075,056 to Quigley *et al.* ("Quigley"). Claims 1-9, 13, 14, 16 and 17 were rejected under 35 U.S.C. 102(b) as disclosed by U. S. Patent No. 5,686,089 to Mitra *et al.* ("Mitra"). Claims 1-10 and 17 were rejected under 35 U.S.C. § 102(b) as disclosed by U. S. Patent No. 5,219,877 to Shah *et al.* ("Shah").

Claim 15 was rejected under 35 U.S.C. § 103 (a) as obvious over U. S. Patent No. 5,686,089 to Mitra *et al*.

Applicants respectfully traverse these rejections to the extent that they are applied to the claims as amended.

As discussed at the interview, the invention is the selection of the class of low to low mid potency steroidal antiinflammatories that can be used in combination with antifungal medication to treat a patient with efficacy but with minimal side effects.

The examiner has pointed to several references in the cited art where it is noted that ultra-high and high potency halogenated or fluorinated anti-inflammatory steroids cause serious side effects.

However, the claims are not drawn solely to low to mid-potency anti-inflammatory steroids but to the combination of the anti-inflammatories with anti-fungal compounds. The claimed formulations have two functions, one of which is to treat a fungal infection and the other of which is to diminish inflammation. The two act by different mechanisms, which may in fact work against each other. It is well known that by decreasing inflammation, one also decreases the anti-infective capabilities of the body. The data presented by Dr. Goldstein establishes that the claimed compositions are both safe and efficacious. No where has the examiner pointed to where one of ordinary skill in the art would expect the combination of this ***selection*** to be safe and efficacious, as opposed to a combination of a low potency hydrocortisone and antifungal or a high potency anti-inflammatory and antifungal. Indeed, the only disclosure in the prior art cited

by the examiner refers to selection of the anti-inflammatory; not to the selection of the antifungal so that the two are together safe and efficacious.

The examiner should re-examine the previously submitted declaration. It is important to note that the prior art did not recognize that the selection of ***both*** the anti-inflammatory and the antifungal are required for efficacy.

As the declaration establishes, many of the patients had previously been treated with strong anti-inflammatories. Counter-intuitively, the stronger anti-inflammatory creates more inflammation, not less, and thinning of the skin.

The claims have been amended as discussed at the interview to define the claimed composition and method as follows:

A topical formulation (support is found at page 2, line 7)

low or mid-potency steroidal antiinflammatories (page 2, lines 7-10; page 3, lines 19-21) (*See* attached printout from the National Psoriasis Foundation website showing the different categories and which products lie within each)

having a higher potency than 1 wt% hydrocortisone (page 5, lines 13-15)

in a concentration between 0.01 wt% and 5.0 wt% (page 4, lines 15-16)

The data presented at the interview demonstrated the unexpected efficacy and lack of side effects of one non-halogenated steroidal antiinflammatory, desonide, in combination with an antifungal. Additional data showing the same unexpected efficacy and lack of side effects for other members of the claimed class of low to low-mid potency steroidal antiinflammatories is

submitted in the attached Declaration under 37 C.F.R. § 1.132 by Dr. Goldstein. Members of the claimed class that have been shown to produce results comparable to a topical cream containing 0.05% desonide and 1% clotrimazole are:

Clotrimazole 1% cream with alclometasone dipropionate 0.05% cream applied twice daily;

Oxicanozole cream 1% with Hydrocortisone cream 2½% applied twice daily;

Econazole cream 1% with fluocinalone acetonide cream 0.01% applied twice daily; and

Econazole cream 1% with alclometasone dipropionate 0.05%, applied twice daily.

Quigley

U.S. Patent No. 6,075,056 to Quigley *et al.* discloses the use of steroidal antiinflammatories with a wide range of potencies (*see* col. 2, lines 7-10; col 4, line 55 to col. 5, line 51). There is no recognition that the potency of the steroidal antiinflammatory is the cause of the side effects and can be eliminated not by changing the carrier as suggested by Quigley but by selecting a narrow class of steroidal antiinflammatories.

Shah

U.S. Patent No. 5,219,877 to Shah *et al.* describes a gel formulation for topical administration including an imidazole antifungal in combination with a mid-potency steroidal antiinflammatory. As described at col. 4, lines 3-16, this class of compounds is not within the claimed class of low and low-mid potency steroidal antiinflammatories.

Mitra

U.S. Patent No. 5,686,089 to Mitra et al. describes treatment with a topical formulation to treat infections with an antimicrobial agent (col. 3, lines 1-49) which can include an antiinflammatory (col. 6, line 65 to col. 7, line 28). There is no teaching of the claimed class of steroidal antiinflammatories, the problems with treatment with mid and high potency antiinflammatories, nor that one should select low or low-mid potency steroidal antiinflammatories.

Robinson

U.S. patent No. 6,444,647 to Robinson, et al. describes a skin care composition containing, as active ingredients, a vitamin B3 compound, farnesol, phytantriol or mixtures thereof, and a carrier. There is nothing teaching one to select low to low-mid potency steroidal antiinflammatories for treatment of skin conditions.

In summary, applicants have demonstrated that the claimed combination unexpectedly provides efficacy and safety, which is neither recognized by nor obvious from the prior art. Allowance of all claims as amended is therefore earnestly solicited.

Respectfully submitted,

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